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(9) Hyde, E. 1982. Personal communication between Edward G. Hyde, Jr., Dr. Elaine Francis and David Dellarco.

(10) McCoy, J. 1981. May 15 Outline of the Protocol for NTP Toxicity Studies of Acetonitrile from Dr. James McCoy to David J. Dellarco.

(11) McCoy, J. 1981. Personal communication between Dr. James McCoy and David J. Dellarco.

(12) Zieger, E. 1982. Personal communication between Dr. E. Zieger and David J. Dellarco.

(13) DuPont, Monsanto, Vistron. 1982. June letter from Wiley M. Branan to Steven D. Newburg-Rinn.

(14) DuPont, Monsanto Vistron. 1982. October letter from Wiley M. Branan to Steven D. Newburg-Rinn.

VI. Public Record

EPA has established a public record for this testing decision (docket number OPTS–42019) which is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday except holidays in Rm. E–107, 401 M St., SW., Washington, D.C. 20460. This record includes basic information considered by the Agency in developing this decision. The record includes:

(1) Federal Register notice containing the designation of acetonitrile to the priority list and all comments on acetonitrile received in response to that notice.

(2) Communications received prior to industry testing proposal consisting of letters, contact reports of telephone conversations and meeting summaries of Agency-industry and Agency-public meetings.

(3) Testing proposal and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and all comments received in response to that notice.

The Agency will supplement the record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003; 15 U.S.C. 2061)

Dated: December 20, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-35276 Filed 12-23-82; 4:48 pm]

BILLING CODE 6560-50-M

[OPTS–42022; BH–FPC 2249–2]

Hexachlorocyclopentadiene; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice constitutes EPA's response to the Interagency Testing Committee's recommendation that EPA require health and environmental effects testing of hexachlorocyclopentadiene (HCCP) under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating rulemaking under section 4(a) to require further health or environmental effects testing of HCCP at this time. EPA does not believe that there is a sufficient basis to find that the current manufacture, distribution in commerce, processing, use, or disposal of this substance may present an unreasonable risk to the environment or of mutagenic or teratogenic health effects, or that there is substantial or significant human exposure or substantial environmental release. In addition, adequate data exist to reasonably predict the chronic health effects of HCCP and an oncogenicity bioassay is under way. Therefore, additional testing for these effects is unnecessary.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Toll free: (800–424–9065), In Washington, D.C.: (554–1404), Outside the USA: (Operator–202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Background

Section 4(e) of TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.;* 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend a list of chemicals for EPA to consider for promulgation of testing rules under section 4(a) of the Act. The ITC may designate substances on the list for priority consideration by EPA. TSCA requires EPA to respond to these designations by initiating rulemaking under section 4(a) or by stating its reasons in the Federal Register for not initiating rulemaking. The ITC designated hexachlorocyclopentadiene (HCCP) for priority consideration in its Fourth Report, published in the Federal Register of June 1, 1979 (44 FR 31866), recommending that HCCP be considered for testing for carcinogenicity, mutagenicity, teratogenicity, and other chronic effects. The Committee also recommended testing consideration for environmental effects, with emphasis on chronic effects in aquatic and terrestrial systems.

The ITC's recommendations were based on evidence of substantial production, potential human exposure in the workplace and more generally as a result of industrial release and disposal, and indications of a potential for persistence and bioaccumulation in the environment. Since that time, new information has become available or is under development that, in EPA's judgment, indicates that further testing of HCCP is not warranted at this time.

This notice provides EPA's response to the ITC's designation of HCCP for testing.

II. Decision Not To Initiate Rulemaking

EPA has decided not to initiate rulemaking to require testing of HCCP under section 4 of TSCA because EPA does not believe that there is a sufficient basis to find that the current manufacture, distribution in commerce, processing, use or disposal of HCCP may present an unreasonable risk of injury to the environment or of mutagenic and teratogenic health effects. Neither has EPA found evidence that there is substantial or significant human exposure to or substantial environmental release of HCCP. In addition, certain new studies have become available since the ITC's report or are under way, making additional testing for chronic and oncogenic effects unnecessary.

A. Release and Exposure

The ITC indicated that annual production of HCCP was greater than 8 million pounds, which the Agency considers to be a substantial quantity. EPA has received confidential information from the manufacturer which leads the Agency to believe that current and expected production continue to be substantial.

Velsicol Chemical Company is the sole producer of HCCP in the United States. It manufactures the chemical at two locations: Marshall, Illinois and Memphis, Tennessee. All of the chemical produced at the Marshall location is used at that location in the production of a registered pesticide product. Part of the HCCP produced at Memphis, Tennessee is used at that site in the production of registered pesticide products and other chemicals, principally chlorendic anhydride (Ref. 5). There is one major customer for the rest (Ref. 6).

In assessing the potential exposure to HCCP, EPA cannot identify any uses other than as a chemical intermediate, almost entirely in the production of a number of pesticides and of chlorendic anhydride. Because of HCCP's extreme acute toxicity (exposure to 1.5 ppm for 7 hours killed 3 of 3 rabbits, 4 of 5 mice, 1 of 4 rats (Ref. 14)), all reactions are carried out in tightly-controlled closed

systems, while workers in potential exposure areas are required to wear respirators and protective clothing (Ref. 6). Velsicol Chemical Company has informed EPA that approximately 157 employees are potentially exposed to HCCP at their facilities (Ref. 6). Representative area and personnel monitoring levels from the HCCP production and use facilities have been made available by Velsicol. Time-weighted average concentrations ranged from 0.0003 to 0.035 ppm, although ceiling values reached 0.2325 ppm when HCCP wastes were being loaded (Ref. 6). Human exposure levels are expected to be significantly lower due to the use of respirators and protective clothing. On the basis of these facts, EPA has concluded that there is not significant or substantial worker exposure to HCCP.

Confidential information submitted by Velsicol indicates that HCCP is released to the air in small quantities from the chemical's manufacture and use as a chemical intermediate. Atmospheric releases of HCCP can be expected to undergo rapid degradation because HCCP's atmospheric lifetime is an estimated 0.2 days (Ref. 1).

HCCP is listed as a toxic waste under the Resource Conservation and Recovery Act (RCRA) (Pub. L. 94–580, as amended). The generation, treatment, storage, and disposal of HCCP-containing wastes are all subject to RCRA regulations (40 CFR Part 261). Producers of toxic wastes in amounts greater than 1,000 kg/month must dispose of said wastes in a RCRA-authorized manner. According to Velsicol, approved disposal of HCCP and associated solid wastes occurs through deep-well injection, incineration, or in regulated landfills (Ref. 6).

Underground injection is subject to permits issued under an Underground Injection Control (UIC) program approved or promulgated under the Safe Drinking Water Act (Pub. L. 95–523, as amended), according to regulations contained in 40 CFR Parts 122, 123, 124, and 146. Underground injection under these regulations is designed to avoid release to the environment.

Process water from HCCP production in Memphis goes to the city sewage plant and is finally discharged into the Mississippi River after treatment (Ref. 6). The Memphis Waste Water Facility monitors levels of HCCP in the effluent; during the months of February through June of 1982, the concentration of HCCP in the sewage treatment plant's effluent ranged from non-detectable to 3.04 ppb, with monthly levels averaging 0.30 ppb (limit of detection is 0.01 ppb) (Ref. 7). Immediate dilution by river water reduces the concentration much further. Furthermore, aqueous photolysis of HCCP occurs extremely rapidly (half-life less than 10 min.) (Refs. 18, 20) and is little affected by suspended sediment (Ref. 18), while the hydrolysis half-life at environmental temperatures is 3–11 days at or below pH 7, and less than 2 hrs. at pH 12 (Refs. 18, 19). These data were not available to the ITC, which had expressed concern about the environmental persistence of HCCP.

The available data on exposure lead EPA to conclude that a section 4(a)(1)(B) finding of significant or substantial human exposure cannot be made for HCCP. Although production volume is clearly substantial, the numbers of workers exposed are low, and the levels of HCCP to which they are exposed are not significant, given the protective measures applied during typical work practice. No TSCA-related consumer exposure is known.

The environmental fate data and the low levels of HCCP release have persuaded EPA that, while HCCP is produced in substantial quantities, its environmental release is not substantial and human exposure through the environment via either air or water will be extremely low. Therefore, EPA further evaluated the ITC's testing recommendations for HCCP in the context of whether a finding of potential unreasonable risk could be made under section 4(a)(1)(A).

B. Health Effects

The ITC recommended that HCCP be considered for testing for carcinogenicity, mutagenicity, teratogenicity and other chronic effects. A 2-year inhalation oncogenicity bioassay is being performed under the National Toxicology Program (NTP) (Ref. 17) and this is expected to provide sufficient data to characterize the carcinogenic properties of HCCP. While a mammalian chronic toxicity bioassay has not been performed on HCCP, an adequate subchronic study is available (Ref. 12). For purposes of section 4 of TSCA, EPA has generally accepted subchronic studies as allowing it to reasonably predict the chronic toxicity of a substance.

Since the ITC's report, teratology studies in three species (Refs. 3, 10), and a number of mutagenicity studies (Refs. 2, 4, 8, 15, 17) have been published in the literature or submitted to EPA as unpublished data. While these studies were not definitive, none of them have yielded any evidence suggesting a potential for these effects that might support a testing requirement under section 4(a)(1)(A) of TSCA. In view of the above, EPA is not initiating rulemaking to require further health effects testing of HCCP at this time.

C. Environmental Effects

The ITC recommended that HCCP be considered for environmental effects testing, placing emphasis on determining HCCP's chronic effects in aquatic and terrestrial systems. The ITC based its recommendations for environmental effects testing of HCCP on indications that it might persist in the environment and bioaccumulate in organisms.

As discussed in Unit II.A on release and exposure, available data indicate that HCCP is not expected to persist in the atmosphere or in water. HCCP's release to soil is closely restricted as discussed in Unit II.A.

A paper cited by the ITC (Ref. 9) indicated that in a model ecosystem some HCCP was retained in organisms exposed to HCCP, but the amount was considerably less for HCCP than for three other chlorinated compounds tested. Although the data in the paper were difficult to interpret, mosquito fish appeared to metabolize HCCP to a considerable extent. In more quantitative experiments, goldfish (Ref. 11) and fathead minnows (Ref. 13), have been found to metabolize and eliminate HCCP readily; the bioconcentration factor for fathead minnows was less than 11, a very low value. Thus, EPA believes that these data allow it to reasonably predict that HCCP will not bioaccumulate to significant levels in the environment, given the small releases of the substances.

The available information, some of which has become available since the ITC made its recommendation, indicates that HCCP is recognized to be a hazard to the environment at low levels with acute and chronic LC_{50}'s for fish and invertebrates at or above 7 ppb (Refs. 13, 16). Because existing data have led to controls that have in turn resulted in extremely low environmental exposures, EPA is unable to find under section 4(a)(1)(A) of TSCA that sufficient HCCP is released to or remains in the environment so that it might present an unreasonable risk of injury to the environment. Under these circumstances, EPA does not believe that additional environmental effects testing can be justified under section 4(a)(1)(A) of TSCA.

III. References

(1) Cupitt LT. 1980. Project summary: Fate of toxic and hazardous materials in the air environment. Washington, DC: Environmental Sciences Research Laboratory, U.S. Environmental Protection Agency (EPA–600/S3–80–084). 7 pp.

(2) Industrial BIO-TEST Laboratories, Incorporated. 1977. Mutagenicity of PCL-Hex incorporated in the test medium tested against five strains of *Salmonella typhimurium* and as a volatilate against tester strain TA-100. IBT No. 8536-10838. Submitted by Velsicol Chemical Corporation.

(3) International Research and Development Corporation. 1978. Teratology study in rats. 163-573. Submitted by Velsicol Chemical Corporation.

(4) Juodeika LF. 1982 (Aug. 11). National Institute of Environemtal Health Science, Bethesda, Maryland 20205. Letter to D. Lockett, Velsicol Chemical Corporation, Washington, D.C.

(5) Levin A. 1982 (Apr. 12). Velsicol Chemical Corporation, Chicago, Illinois 60611. Transcribed telephone conversation with S.D. Newburg-Rinn, Assessment Division, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C.

(6) Levin A. 1982 (Apr. 19). Velsicol Chemical Corporation, Chicago, Illinois 60611. Letter to S. Newburg-Rinn, Assessment Division, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C.

(7) Levin A. 1982 (Oct. 12). Velsicol Chemical Corporation, Chicago, Illinois 60611. Letter to S. Newburg-Rinn, Assessment Division, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C.

(8) Litton Bionetics, Incorporated. 1978. Mutagencity of hexachlorocyclopentadiene in the mouse dominant lethal assay. LBI Project No. 20862. Submitted by Velsicol Chemical Corporation.

(9) Lu PY, Metcalf RL, Hirwe AS, Williams W. 1975. Evaluation of environmental distribution and fate of hexachlorocyclopentadiene, chlordene, heptachlor and heptachlor epoxide in a laboratory model ecosystem. J. Agric. Food Chem. 23:967-973.

(10) Murray FJ. Schwetz BA, Balmer MF, Staples RE. 1980. Teratogenic potential of hexachlorocyclopentadiene in mice and rabbits. Toxicol. Appl. Pharmacol. *53*:497-500.

(11) Podowski A, Khan MAQ. 1979. Fate of hexachlorocyclopentadiene in goldfish (*Carassius auratus*). Paper persented at the Amer. Chem. Soc. Meetings, Honolulu, HI, April 1979.

(12) Rand GM, Nees PO, Calo CJ, Alexander DJ, Clark GC. 1982. Effects of inhalation exposure to hexachlorocyclopentadiene on rats and monkeys. J. Toxicol. Environ, Health *9*:743-760.

(13) Spehar RL. Veith GD, DeFoe DL, Bergstedt BV. 1979. Toxicity and bioaccumulation of hexachlorocyclopentadiene, hexachloronorbornadiene and heptachloronorbornene in larval and early juvenile fathead minnows, *Pimephales promelas*. Bull, Environ. Contam. Toxicol. *21*:576-583.

(14) Treon JF, Cleveland FP, Cappel J. 1955. The toxicity of hexachlorocyclopentadiene. Amer. Indust. Hyg. Assoc. Bull. *11*: 459-472.

Velsicol Chemical Corporation. 1978. TSCA sec. 8(e) submission 8EHQ-0378-0102. Litton Bionetics, Incorporated, 1978. Mutagenicity evaluation of hexachlorocyclopentadiene in the mouse lymphoma forward mutation assay. LBI project No. 20839. Washington, D.C. Office of Toxic Substances, U.S. Environmental Protection Agency.

(16) USEPA. 1980. U.S. Environmental Protection Agency. Office of Water Regulation and Standards. Ambient water quality criteria for hexachlorocyclopentadiene. Washington, D.C.: U.S. Environmental Protection Agency. EPA 440/5-80-055. PB81-117665.

(17) USPHS. 1982. U.S. Public Health Service. National toxicology program: Fiscal year 1982 annual plan. Washington, D.C.: Department of Health and Human Services.

(18) Wolfe NL, Zepp RG. Schlotzhauer P, Sink M. 1982. Transformation pathways of hexachlorocyclopentadiene in the aquatic environment. Chemosphere 11:91-101.

(19) Yu CC, Atallah YH. 1977. Hex hydrolysis at various pH and temperature. Project No. 482428, Report No. 2. Submitted by Velsicol Chemical Corporation.

(20) Yu CC, Atallah YH. 1977. Photolysis of hexachlorocyclopentadiene. Project No. 482428. Report No. 4. Submitted by Velsicol Chemical Corporation.

IV. Public Record

EPA has established a public record for this testing decision (docket number OPTS-42022) which includes:

(1) Federal Register notice containing the designation of hexachlorocyclopentadiene to the Priority List.

(2) Communications (public).

(a) Non-confidential letters.

(b) Confidential letters (separately held).

(c) Contact reports of telephone conversations.

(d) Meeting summaries.

(3) Published and unpublished data.

This record which includes basis information considered by the Agency in developing this decision is available for inspection in the OTS reading room from 8:00 a.m. to 4:00 p.m. on working days in Rm. E-107, 401 M St., SW., Washington, D.C. 20460.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2601))

Dated: December 20, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-35277 Filed 12-23-82; 4:54 pm]

BILLING CODE 6560-50-M

(OPTS-42017; TSH-FRI 2238-1)

Methyl Isobutyl Ketone and Methyl Ethyl Ketone; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Fourth Report of the Interagency Testing Committee (ITC), published in the Federal Register of June 1, 1979, (44 FR 31866) the ITC designated methyl isobutyl ketone (MIBK) and methyl ethyl ketone (MEK) for priority consideration for health effects testing. Following publication of the ITC report, additional testing data were made available to EPA, and the major U.S. manufacturers of MIBK and MEK presented to the EPA plans for testing further the health effects of these chemicals. The Agency has concluded that the existing data are sufficient to evaluate some of the effects recommended for testing by the ITC. In other cases, the EPA believes that testing recommended by the ITC is not warranted by the available data. Finally, EPA has tentatively decided to accept the industry proposal in lieu of rulemaking to fill the remaining data gaps of concern to the Agency. Consequently, the EPA is not, at this time, initiating rulemaking to require health effects testing of MIBK and MEK. This notice constitutes EPA's response to the ITC as required by section 4(e) of the Toxic Substances Control Act. Interested persons are invited to comment on EPA's Conclusions as to what testing is needed and on the adequacy of the industry program.

DATE: All comments must be submitted by February 14, 1983.

ADDRESS: Written comments should bear the document control number OPTS-42017 and should be submitted in triplicate to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St. SW., Washington, D.C., 20460.

The administrative record supporting this action is available for public inspection in Rm. E-107 at the above address from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St. SW., Washington, D.C., 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 4(a) of the Toxic Substances Control Act (TSCA) authorizes the EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data